



Improving the lives of people suffering from mental illness and substance use disorders



Pareto Healthcare Conference Sep 1-2, 2021

Nasdaq Stockholm: ORX
US OTC Market: ORXOY (ADR)

Legal Disclaimer

- This presentation, which is personal to the recipient, has been prepared and produced by Orexo AB (publ) ("Orexo") solely for the benefit of investment analysis and may not be used for any purpose other than assessment of investments concerning Orexo. Unless otherwise stated, Orexo is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form the basis of, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of Orexo
- The shares of Orexo have not been registered under the U.S. Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States (as such term is defined in Regulation S under the Securities Act) except pursuant to an exemption from, or a transaction not subject to, the registration requirements of the Securities Act or unless registered under the Securities Act.
- The information in this presentation has not been independently verified. No representation or warranty, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information or opinions contained herein. None of Orexo, any of its shareholders, or any of their respective subsidiary undertakings or affiliates or any of such person's directors, officers or employees, advisers or other representatives, accepts any liability whatsoever (whether in negligence or otherwise) arising, directly or indirectly, from the use of this presentation or otherwise arising in connection therewith.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and Orexo expressly disclaim any obligation or undertaking to release any update of, or revisions to, any forward-looking statements in this presentation as a result of any change in our expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation is not a prospectus in accordance with the Swedish Financial Instruments Trading Act (Sw. lagen (1991:981) om handel med finansiella instrument) or any other Swedish laws or regulations. Neither the Swedish Financial Supervisory Authority (Sw. Finansinspektionen) nor any other Swedish regulatory body has examined, approved or registered this presentation.

Orexo – focusing on the large and growing space of treatment of mental illness

- Developed four commercial pharmaceutical products with worldwide approval
- Commercial presence in the US with own field force
- Strong financial position
- Strategic focus on portfolio expansion through R&D and licensing/M&A
- International experienced management team and board of directors

Profitable US Pharma operations

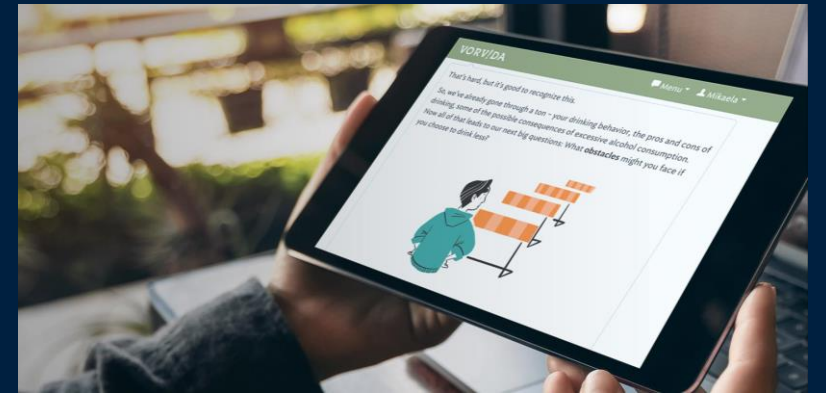
Three digital therapies for treatment of AUD, OUD and depression

Lead pipeline product OX124 a new rescue medication for overdoses caused by synthetic opioids

- Net revenues FY'20 SEK 623 million
- EBITDA FY'20 SEK 347 million
- EBIT Margin FY'20 53 percent
- > 40 million potential patients (pre-Covid)
- Strong scientific evidence of clinical effect
- New frontier in patient care and following a mega-trend in health care
- > USD 300 million market
- Synthetic opioids behind 74% of fatal OD¹
- Positive results from first clinical trial
- Expected US launch 2023

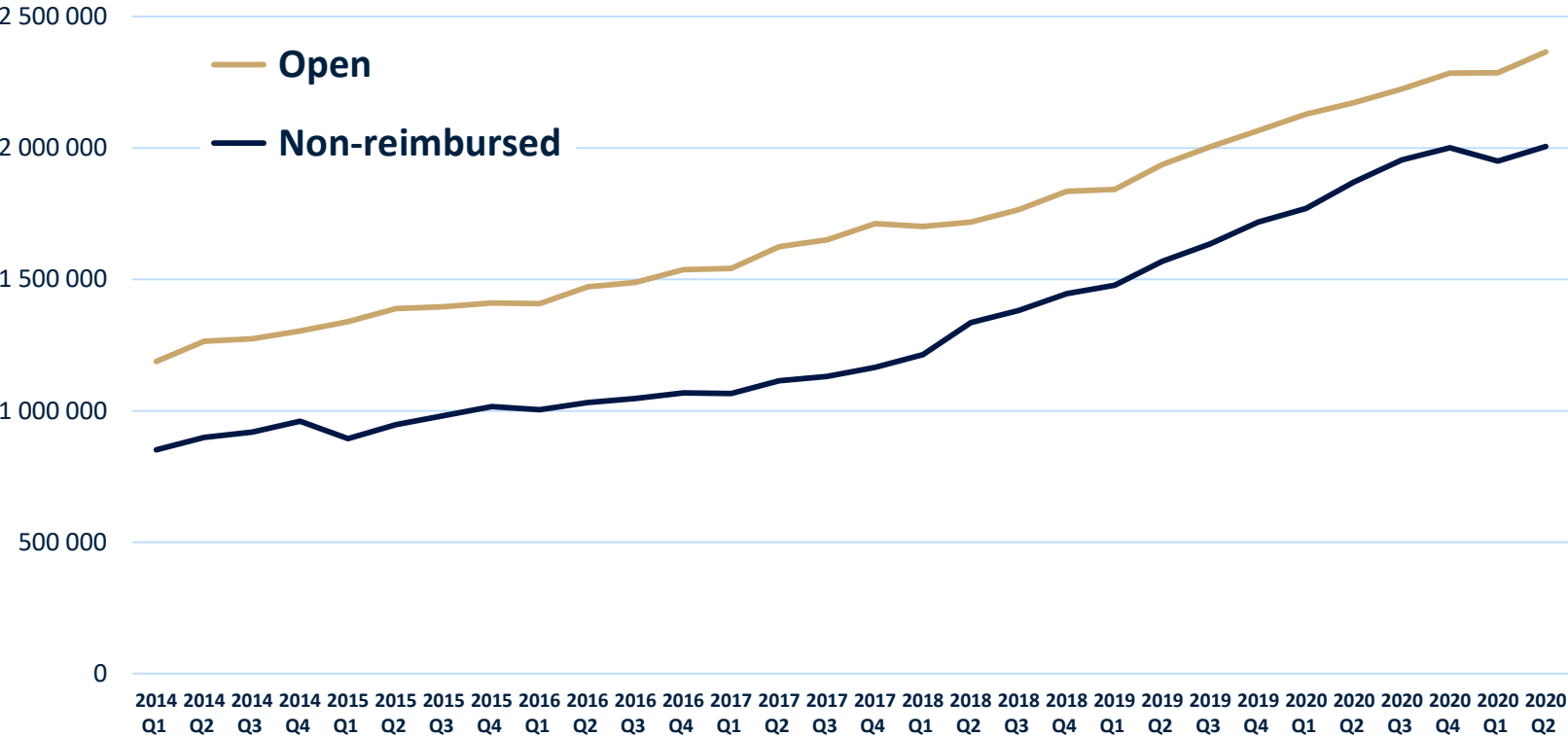
**ZUBSOLV® continues to be a
strong cash contributor**

orexo



Market volume reaching new highs in Q2 2021, with YoY growth rate decelerating due to drop in Q1 2021

Market Volume Sales, quarterly NTRx



Q2'21 vs Q2'20 Growth

Total Market: +8%

The growth is driven by the Public segment, although Public growth is lower than recent years.

By Segment

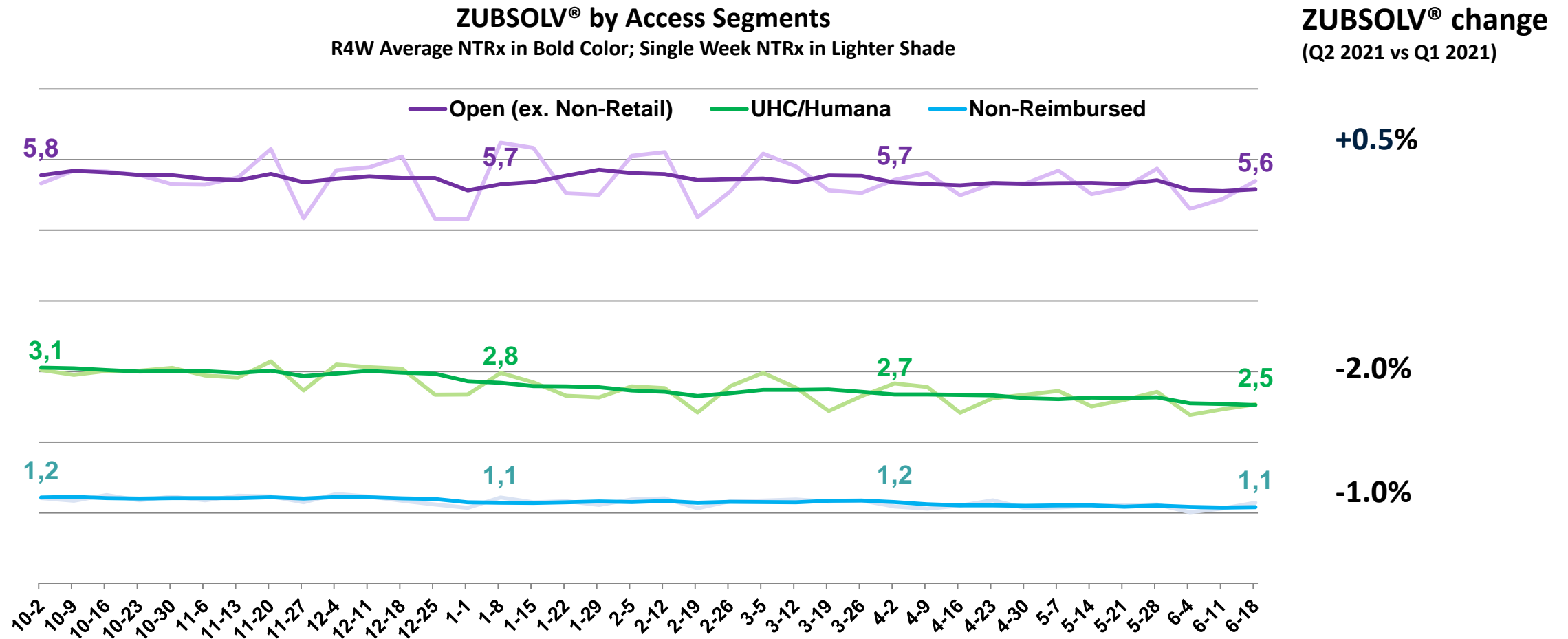
+9%

+7%

2020 Q2 volume estimated
Note: NTRx = Total prescriptions adjusted to 30 tablet/film scripts
Note: Historical quarters slightly restated due to IMS recategorization; LTC channel data available from Q2'18
Source: IQVIA XPO

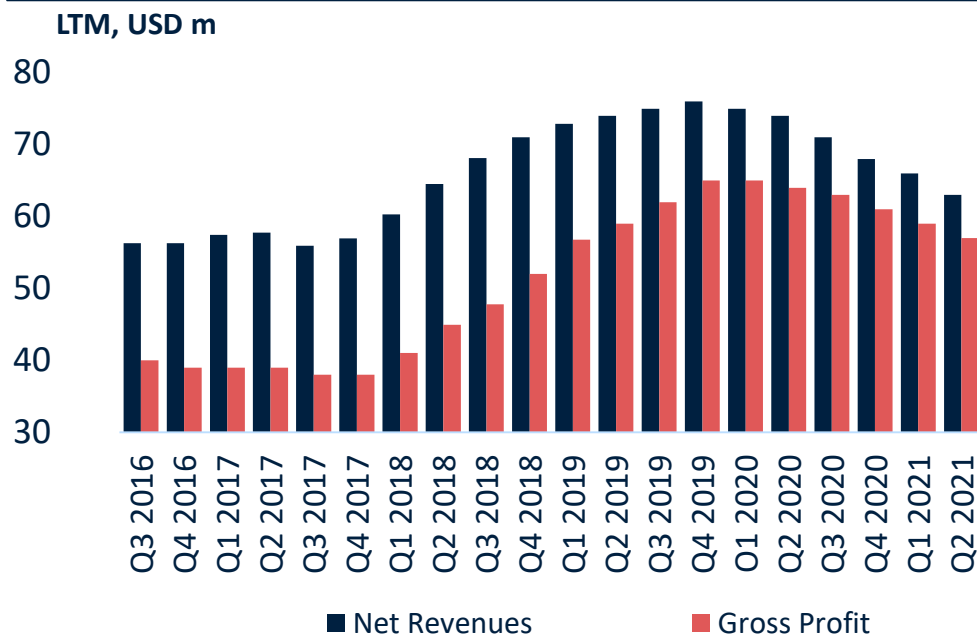
ZUBSOLV® overall volume stable supported by resilience in Open segment

UHC/Humana continue to decline, but the decline is decelerating

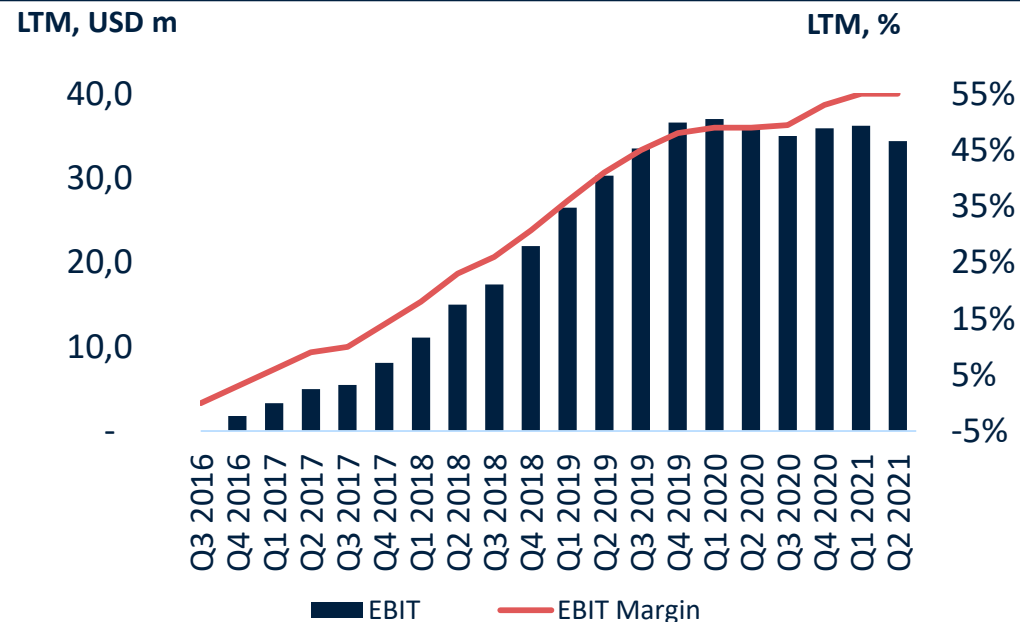


Q221 - US Pharma Operating Margin (LTM) 55%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales declined to USD 62.9 m from USD 73.6 m in Q220
- EBIT contribution of USD 34.4 m with slight decrease from USD 36.2 m in Q220 driven by lower sales and increased admin costs due to Subpoena
- US Pharma EBIT margin of 54.6% LTM in Q221 increasing from 49.1% in Q220, EBIT margin for H1 2021 reached 50.5%

Note: COGS converted from SEK to USD using monthly average exchange rates for the period.

While ZUBSOLV® is facing multiple growth drivers, Covid-19 continues to create a challenging environment

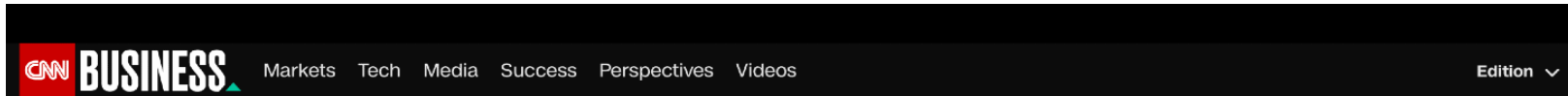
Comments to Q2 QoQ development

- The development in ZUBSOLV's core payer segment, the Commercial segment, it still negatively impacted by Covid-19 and the fluctuating unemployment rate
- The demand in former exclusive plans, Humana and United Health Group, continued to decline but at the slowest pace since the formulary changes in 2019
- Sales force access to prescribers increased in the quarter but is not yet back on pre-Covid-19 activity levels

ZUBSOLV® growth drivers

- Multiple comprehensive activities on-going on federal and state levels that will increase access to treatment
- Coverage in Kentucky Medicaid brings Public payer access from 34% to 42%. Other market access confirmed for H2 2021
- Commercial segment returning to pre-covid growth levels
- The launch of modia™ as a treatment complement to ZUBSOLV® will open up for new sales routes and market segments

Opioid litigations and settlements creates significant increase in resources available to treat OUD and open up new opportunities



Three opioid distributors settle New York lawsuit for \$1.1 billion

By Evan Simko-Bednarski, CNN Business

Updated 1654 GMT (0054 HKT) July 20, 2021

THE DENVER POST

MANAGE SUBSCRIPTION
SIGN UP FOR NEWSLETTERS
DIGITAL REPLICATION EDITION
OBITUARIES

NEWS > HEALTH • News

Here's how Colorado plans to distribute \$400 million in opioid settle funds

Money comes from historic multistate settlements with drugmakers and distributors



orexo



Ohio AG announces \$26B settlement with major drug companies that fueled opioid epidemic

The settlement was made with three of the largest distributors of opioids and Johnson & Johnson.

By FOX19 Digital Staff

Published: Jul. 21, 2021 at 8:41 PM CEST



News

Radio & Podcasts

TV

Arts

Events

Education

Pennsylvania would get \$225M in revamped opioid agreement

By Associated Press · July 8, 2021

Expanding the
commercialization model
in DTx

VORV!DA[®]
deprexis[®]
modia[™]

DTx - an attractive opportunity to diversify the company and drive future growth

- Continuous increase in scientific evidence of the value from digital health products
- Covid-19 has significantly accelerated the utilization of non face to face interactions between healthcare providers and patients
- Digital health solutions offer a superior monitoring of treatment outcome and enables value based solutions

Strong synergies with the current US commercial platform with a focus on opioid use disorder and treatment with ZUBSOLV® (bup/nal) and R&D pipeline

Digital therapeutics is in its infancy - while the potential is significant, several hurdles need to be addressed before the market takes off

Commercialization

- Optimal pathways to commercialize and scale DTx are still uncharted

Pricing

- Entry barriers are low for offerings without clinical evidence, and thus payors need to establish appropriate assessment criteria to enable price differentiation

Reimbursement

- Many payors still to establish payment and reimbursement processes

Disruptive technology

- While digital therapies have been proven clinically, speed of adoption is still unknown as for any new therapeutic approach

Orexo will continue to assess the business model, the potential and the investment levels required to capture new opportunities at the appropriate time




Orexo Digital Therapeutics (DTx)

17 million patients in the US suffered from depression pre-Covid

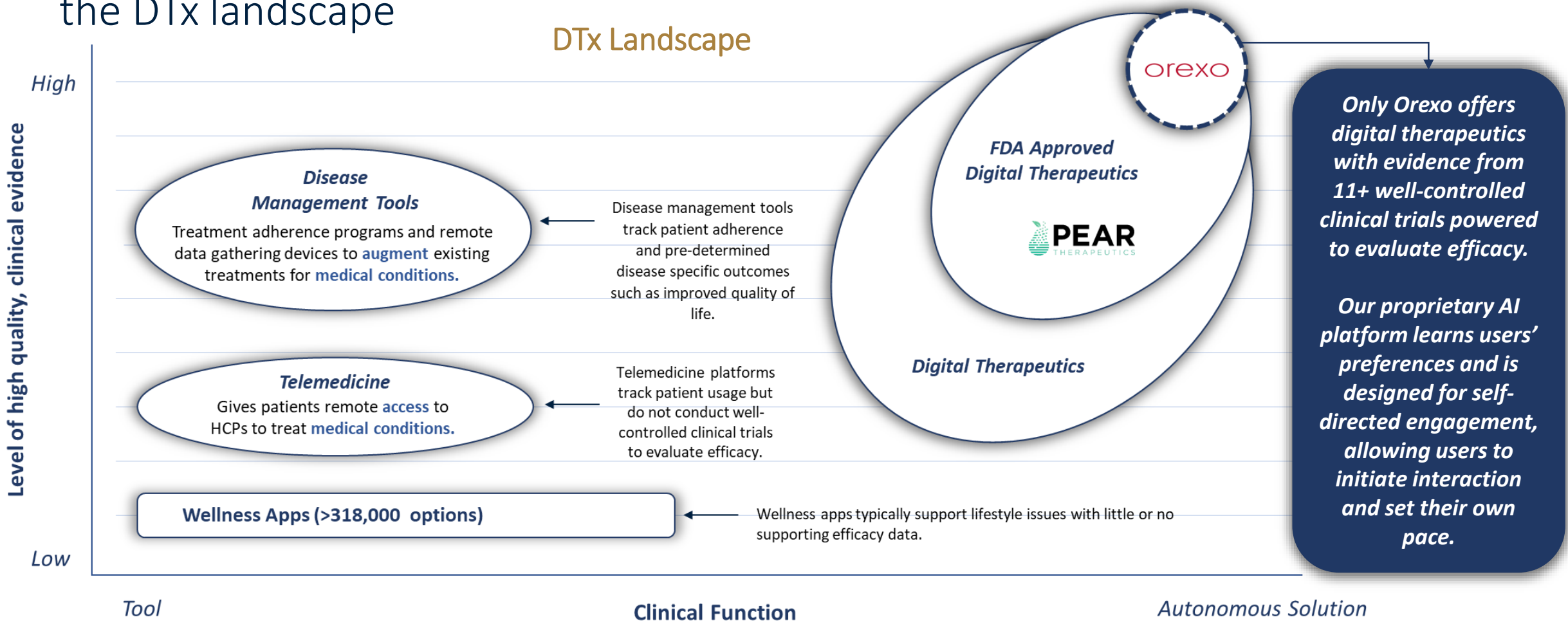
16 million Americans who are heavy drinkers and should be treated

Of the 10 million people misusing opioids only few have access to the psychosocial support they need as part of their recovery

orexo

	<p>Twelve weeks of digital cognitive behavioral therapy for mild to moderate to severe depression</p> <p>One of the most studied digital therapies in depression with 11+ original trials in over 2,800 patients</p>
	<p>Twenty-four week duration digital cognitive behavioral therapy for problematic drinking</p> <p>Launching under Enforcement Policy for Digital Health Devices for treating psychiatric disorders during Covid-19 Public Health Emergency</p>
	<p>Twenty-four week digital therapy to provide support for patients with opioid use disorder</p> <p>Launching in 2021 under US FDA Enforcement Policy for Digital Health Devices for treating psychiatric disorders during Covid-19 Public Health Emergency</p>

The Orexo portfolio has unparalleled clinical evidence and functionality in the DTx landscape



modia™ randomized clinical trial initiated in 400 patients

Outcome essential for differentiation enabling market access and appropriate regulatory FDA classification



400 participants at 35 sites across the US

The randomized, open-label, parallel-group study will evaluate whether the use of modia™ in combination with sublingual buprenorphine/naloxone background therapy is **superior to sublingual buprenorphine/naloxone alone to reduce illicit opioid use**

The RCT is expected to end H2 2022 and reach a total investment of USD 9 million during H2 2021-2022

Multiple commercial contracts signed with healthcare providers...

.....of which one with a Integrated Health Distribution Network – Trinity Health North Dakota



New Commercial agreements signed in Q2

- Trinity Health North Dakota
- NYC clinic
- Mental health hospital in St Louis
- Start-up company providing telemedicine to health care professionals

Agreements are an inspiring model for other commercial leads

- Advanced discussions with two additional larger health care providers with multi-state operations in the US
- Advanced discussions with a large industrial company and their insurance company of a pilot test
- Advanced discussions with leading telemedicine company within mental health in the US
- Advanced discussion with several additional smaller healthcare providers

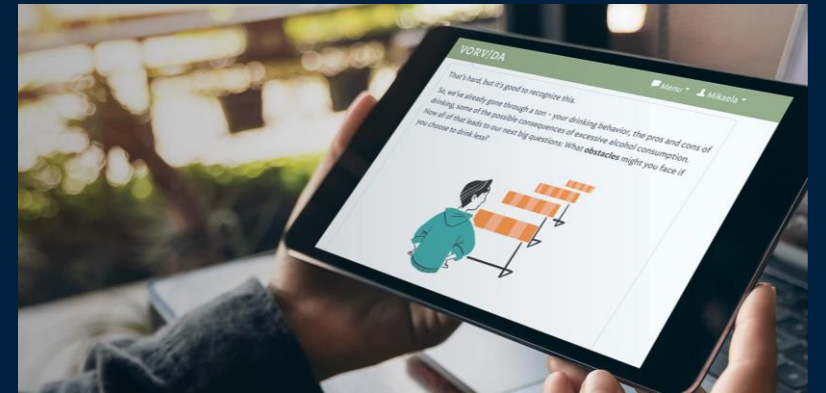
The Sober Grid partnership will reach 300 000 individuals struggling with mental health issues

- Sober Grid is the **largest global digital network** for people trying to reach, or that are in, recovery from addiction
- **The partnership will evolve in three phases**
 - Phase 1: deprexis® and vorvida® will be made available through Sober Grid's certified peer coaches (*Q3 2021*)
 - Phase 2: deprexis® and vorvida® will be made available to the full Sober Grid network of 300 000 users (*Q4 2021*)
 - Phase 3: Orexo and Sober Grid will offer deprexis® and vorvida® together with Sober Grid's coaching services to other customers (*H1 2022*)
- The partnership will **kick-off in August 2021**



OX124 - overdose rescue medication, approaching US launch in 2023

orexo



OX124 - a new stronger overdose rescue medication with naloxone

Expected launch in 2023

The unmet need

In 2020, the number of drug-related overdose deaths reached more than 92,000 for the first time in history, an increase of 31%. 74% of these deaths were caused by opioids and within the opioid-related deaths synthetic opioids accounted for the vast majority (81%)¹

Our aim

A rescue medication that is stronger and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids


The potential

70-110 million USD net sales (US market)



¹ Center of Disease Control

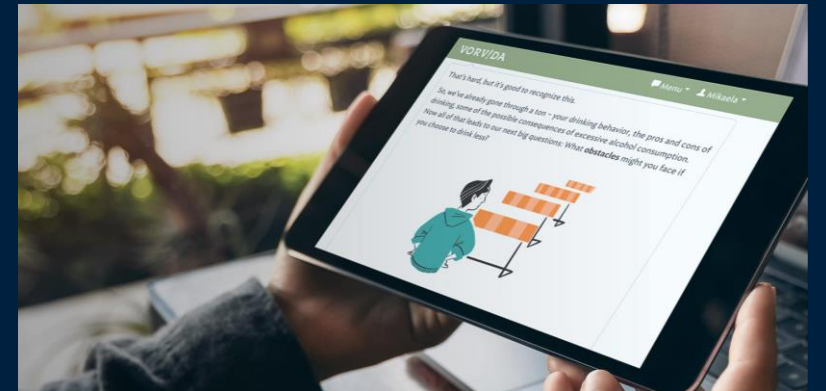
Good progress YTD with the aim to launch in the US in 2023

Progress January-July....onwards
 Commercial supply chain established	 Perform the pivotal bridging study
 12 month stability study initiated	 File the New Drug Application with the FDA
 Pivotal trial initiated	 Launch in the US

The technology developed for OX124 and all learnings from the development process are now being applied on new APIs and tested *in vitro*

Financial information & legal update

orexo



A transformative last 12 months period building for future growth

Numbers reflects loss in Abstral® royalty due to patent expiration and investments in the build-up of DTx venture

Group net revenues LTM Q2'21	US Pharma net revenues LTM Q2'21
SEK 585 m	SEK 539 m
Group EBITDA LTM Q2'21	US Pharma EBIT LTM Q2'21
SEK -76 m	SEK 295 m
Cash position	US Pharma EBIT Margin (SEK)
SEK 680 m	55 %

LTM, Last Twelve Months
Denomination currency is SEK

No changes in the two ongoing legal processes in Q2, except for **two new patents issued for ZUBSOLV®**

Subpoena

- On July 14, 2020 Orexo US received subpoenas to provide US Authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests.
- Orexo has engaged a US counsel to advise the company and prepare for any further requests or actions from the authorities

No further information or requests have been received from the authorities after July 14th 2020

Patent infringement litigation against Sun Pharma

- Orexo on September 13 filed a patent infringement action in the US District Court for the District of New Jersey, against Sun Pharmaceuticals. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds ZUBSOLV's patents to be invalid or not infringed, whichever occurs first
- Two new patents issued for ZUBSOLV®
- Orexo currently has **nine** patents listed in the Orange Book with expiration dates from Dec. 2027 to Sep. 2032

Orexo has previously successfully defended the ZUBSOLV® patents and is well prepared for a new process with Sun

1 Abbreviated New Drug Application

Summary - Strong value drivers for long-term growth

Future value drivers	<ul style="list-style-type: none">➤ Product portfolio addressing large and growing markets	<ul style="list-style-type: none">➤ Strong cash conversion to support growth
<ul style="list-style-type: none">➤ Leveraging our US commercial excellence	<ul style="list-style-type: none">➤ Expanding pipeline targeting unmet medical needs	<ul style="list-style-type: none">➤ Entering digital therapeutics, a new evidence-based frontier in patient care

Thank You



IR Contact: Lena Wange, IR & Communications Director, ir@orexo.com. For more information please visit www.orexo.com.

You can also follow Orexo at Twitter [@orexoabpubl](https://twitter.com/orexoabpubl), LinkedIn and YouTube   